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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,858	08/28/2003	08/28/2003 Mitsuo Yasushi 041465-5197		6382
9629	9629 7590 08/19/2005		EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW			ALTER, ALYSSA M	
WASHINGTON, DC 20004			ART UNIT	PAPER NUMBER
	•		3762	

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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miner. (a). 37 CFR 1.121(d). m PTO-152.	
_· ional Stage	

	Application No.	Applicant(s)				
	10/649,858	YASUSHI ET AL.				
Office Action Summary	Examiner	Art Unit				
	Alyssa M. Alter	3762				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>28 August 2003</u> .						
2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-16</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-16</u> is/are rejected.						
· · · · · · · · · · · · · · · · · · ·	7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers						
9) The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>28 August 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The path or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a)⊠ All b)□ Some * c)□ None of:						
1.☑ Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)	·					
1) X Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ate				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/28/03 & 1/16/04.	5)  Notice of Informal P 6)  Other:	atent Application (PTO-152)				

#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 12-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The software operating on a computer of claim 12 is functional descriptive material since it does not define any structural and functional interrelationships between the computer software program and other claimed elements of a computer, which permits the computer program's functionality to be realized. See MPEP 2106 IV.B.1. and MPEP 2106 IV.B.1.(a). The examiner recommends changing the preamble to be --A computer readable medium encoded with software for measuring heart rate-- in order to overcome this rejection.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 6 and 12-15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites the limitation "wherein the identification information". There is insufficient antecedent basis for this limitation in the claim. The examiner recommends changing claim 6 to be dependent on claim 5, instead

of claim 1. As to claims 12-15, the examiner is unsure of what the Applicant means by a "computer data signal".

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 1. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Steinhaus et al. (US 5,215,098). Steinhaus et al. discloses a method and apparatus for storing a representation of a cardiac signal by compressing the data.

As to claims 1, 7-8, 10 and 16, figure 1 displays the "digital correlator or scanning" correlator, shown generally at 5, in accordance with the present invention. This Figure exemplifies the usage of a scanning correlator as a basic control element in a system for compressing and storing cardiac electrical signals by sampling electrocardiograms and comparing the signal with a stored signal composed of averaged normal sinus rhythm waveforms and averaged waveforms which exemplify cardiac rhythms other than normal sinus rhythm. Cardiac heartbeat signals are sensed by electrodes (not shown), which are affixed to the left ventricle of the heart 15 and electrically connected to leads 10 extending to the digital correlator electronics (not shown) contained within a case 18. The scanning correlator detects cardiac signals using one of the configurations standard in cardiac pacing: bipolar, unipolar tip-case or unipolar ring-case" (col. 5, lines

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26-42). Since the "cardiac heartbeat signals are sensed by electrodes", the examiner considers the electrodes to be the acquisition unit or acquiring device.

As to claims 1 and 8, "Temporary buffer 80 and storage controller 85 provide for the storage of compressed or noncompressed waveforms for some scanning compressed correlator applications. The correlator 50 correlates the input signal with a template segment of previously sampled and averaged normal sinus rhythm wave for data (NSR)"(col. 9, lines 8-14). The examiner considers the correlator to be the cross-correlation processing unit or performing device and the buffer or storage to be the database.

As to claims 1, 5, 8 and 11, "An external controller (not shown), such as a microprocessor, may select one or more particular templates for correlation at a particular time. Thus, the data compressor may correlate a single incoming signal sequence with a number of templates for the purpose of classifying the sequence as a particular type of rhythm or morphology. For example, the digital correlator first correlates the cardiac signal with the normal sinus rhythm template in block 50 (FIG. 1), then compares the correlator result with a predetermined normal sinus rhythm threshold value in block 55"(col. 13, lines 46-56). Since the microprocessor selects one or more templates from the database, the examiner considers it to be a search unit. Also, since the information is classified, there is implicitly a setting unit.

As to claims 2-3 and 9, also since the search unit, microprocessor, is used in conjunction with the cross-correlation processing unit, correlator, the examiner considers the search unit to comprise the cross-correlation processing unit which

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includes template matching, template averaging and calculating the similarities between the waveforms and the templates.

As to claim 1 and 8, "The data compression procedure of block 45 analyzes a predetermined number of input samples to find the value of the sample having the maximum excursion, positive or negative, from the most recent output sample" (col. 7, lines 20-24). The examiner considers the data compressor 45 to be the calculation unit or calculating device.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 1. Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinhaus et al. (US 5,215,098). Steinhaus et al. discloses the claimed invention except for the system being comprised of a computer readable medium or software. It is well known in the art that software is interchangeable with hardware elements for implementing diagnostic data processing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical device as taught by Steinhaus et al. to be executed by a computer implemented programs as a mere choice in engineering design.

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# Claim Objections

1. Claim 1 is objected to because of the following informalities: "electrocardiogram. waveform" is incorrect punctuation. Appropriate correction is required.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- 1. Ambos et al. (US 4,680,708) discloses a method and apparatus for analyzing electrocardiographic signals.
- 2. Sadeh (US 4,732,158) discloses a methid and apparatus for monitoring electrocardiogram (ECG) signals.

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Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-

4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number

for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

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you have questions on access to the Private PAIR system; contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M Alter Examiner Art Unit 3762

PRIMARY EXAMINER

\$117/05